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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,537	08/01/2003	Paul V. Goode JR.	DEXCOM.024A	2669
20995	7590	12/21/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			NGHIEM, MICHAEL P	
			ART UNIT	PAPER NUMBER
			2863	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/632,537

Applicant(s)

GOODE ET AL.

Examiner

Michael P Nghiem

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-9, 11-18, 21-27, 29, 31, 32 and 34-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 18, 27, 38-41 and 46-49 is/are allowed.
- 6) ☒ Claim(s) 2-8, 11-17, 21-26, 29, 31, 32, 34-37 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11-30-04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Withdrawal of Allowability***

1. The indicated allowability of claims 6, 7, 15, 16, 24, 25, 29, 31, and 32 is withdrawn in view of the newly discovered reference(s) to Bartkowiak et al. (US 2003/0235817). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-8, 11-17, 21-26, 29, 31, 32, 34-37, and 42-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Bartkowiak et al. (US 2003/0235817).

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Regarding claims 6, 7, 15, 16, 24-26, 29, 31, and 32, Bartkowiak et al. discloses a method and system for evaluating clinical acceptability of at least one of reference and sensor analyte data (paragraph 0326, lines 16-21), the method comprising:

- receiving a data stream from an analyte sensor (data received by analyte monitoring device, paragraph 0326, line 19), including one or more sensor data points (paragraph 0271, lines 3-4);

- receiving reference data from a reference analyte monitor (paragraph 0326, lines 16-18), including one or more reference data points (paragraph 0326, line 17);

- evaluating the clinical acceptability at least one of said reference and sensor analyte data using substantially time corresponding reference or sensor data (paragraph 0326, lines 16-23), wherein said at least one of said reference and sensor analyte data is evaluated for deviation from its substantially time corresponding reference or sensor data (paragraph 0326, lines 21-23) and clinical risk associated with that deviation based on the glucose value indicated by at least one of said sensor and reference data (paragraph 0332, lines 1-2).

Regarding claims 2, 11, 34, and 42, Bartkowiak et al. discloses providing an output (display component, paragraph 0355, lines 8-12) through a user interface (user interface of display) responsive to said clinical acceptability evaluation (paragraph 0355, lines 4-12).

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Regarding claims 3, 4, 12, 13, 21, 22, 35, 36, 43, and 44, Bartkowiak et al. discloses that the step of providing an output includes alerting the a user based on said clinical acceptability evaluation (paragraph 0128, lines 4-5).

Regarding claims 5, 14, 23, 37, and 45, Bartkowiak et al. discloses that the step of alerting the user interface includes at least trend information (paragraph 0267, lines 1-6).

Regarding claims 6, 15, and 24, Bartkowiak et al. further discloses that the step of evaluating the clinical acceptability includes using one of a Clarke Error Grid (paragraph 0326, lines 13-15).

Regarding claims 7, 16, and 25, Bartkowiak et al. further discloses requesting additional reference data if said clinical acceptability evaluation determines clinical unacceptability (reference data for 5 categories, paragraph 0326, lines 16-20).

Regarding claims 8 and 17, Bartkowiak et al. discloses repeating the clinical acceptability evaluation step for said additional reference data (deemed to be repeated for other categories).

***Allowable Subject Matter***

3. Claims 9, 18, 27, 38-41, and 46-49 are allowed.

***Reasons For Allowance***

4. The combination or method as claimed wherein matching reference data to substantially time corresponding sensor data to form a matched pair after the clinical acceptability evaluation step (claims 9, 18, 27) is not disclosed, suggested, or made obvious by the prior art of record.

***Response to Arguments***

5. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

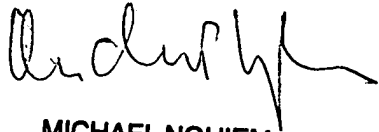
***Contact Information***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P Nghiem whose telephone number is (571) 272-2277. The examiner can normally be reached on M-H.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571) 272-2269. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**MICHAEL NGHIEM**  
**PRIMARY EXAMINER**

Michael Nghiem

December 15, 2004